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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,537	06/21/2001	Myron Spector	1194-176	2633
6449	7590	12/10/2003	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			GUCKER, STEPHEN	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,537

Applicant(s)

SPECTOR ET AL.

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. and further in view of Stensaas et al. (US 4,778,467, "Stensaas"). The '278 patent discloses a single sheet of a resorbable sidewall material consisting essentially of a single layer collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, this sheet material further having a fibrous inner surface opposite the smooth barrier surface (column 1, line 51 to column 2, line 6) derived from collagen membrane peritoneal tissue (column 2, lines 52-60). This single layer collagen sheet material is identified as Bio-Gide® by the instant specification (page 3, lines 6-11), thereby meeting the limitations of the instant claims. Shimizu discloses a nerve regeneration tube comprising of at least three sheets of collagen (column 6, line 48 to column 7, line 50, and as indicated by Applicant's response filed 2/27/03, Paper No. 10, Amendment B, page 4). Neither the '278 patent or Shimizu explicitly disclose a reasonable expectation of success of making a collagen

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nerve regeneration tube out of a collagen sheet of membrane. Both Hentz et al. and Rosen et al. teach in their abstracts the feasibility and likelihood of success of making collagen tubes out of collagen sheets or membranes. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single sheet collagen material of the '278 patent to make a nerve regeneration tube out of collagen as taught by Shimizu because Shimizu employs at least three sheets of collagen to produce his nerve regeneration tube and by using a single sheet of collagen with the attractive features (one side smooth and inhibits cell permeation, the other side fibrous to promote biological regrowth) taught by the '278 patent, a simpler nerve regeneration tube can be produced that uses less material (single sheet as opposed to at least three sheets of collagen), is quicker and easier to produce, and would have the further advantage of economic savings due to lowered costs of production by reducing the need for at least three sheets of collagen to a single sheet of collagen. The combined references also establish a *prima facie* case of obviousness because the collagen material of the '278 patent has desirable features such as a smooth surface to inhibit cell adhesion on the outside with a fibrous surface to support cells on the inside and simply forming a tube out of this two-sided collagen material is *prima facie* obvious given that collagen nerve regeneration tubes were in use at least as way back as the 1980s, and the '278 patent collagen material is used as a single sheet to make a collagen nerve regeneration tube as opposed to at least three sheets of collagen which are used in the prior art of record.

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Finally, the advantageous characteristics of the two-sided collagen material of the '278 patent would suggest to and motivate the ordinary artisan to fashion the collagen material into a tube with a smooth outside and fibrous inside in order to promote axonal regeneration in the interior of the tube as indicated by Shimizu (column 7, line 55 to column 8, line 13; column 8, line 40 to column 9, line 63). None of Geistlich or Shimizu or Hentz et al. or Rosen et al. explicitly teach methods of forming tubes from collagen sheets, although Shimizu does teach a collagen nerve regeneration tube and Hentz et al. and Rosen et al. do describe making tubes from collagen sheets. Stensaas teaches methods of forming tubes for nerve regeneration (Figures 1 and 3A-3B, column 10, line 3 to column 11, line 5) with or without silicone rubber adhesive that meet the limitations of the instant claim (also see column 9, lines 1-16 and column 16, lines 54-66 (Figures 7A-7B) for overlapping edges). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the teachings of Stensaas to make various kinds of tubing (opposed edges, overlapping edges, etc.) out of a collagen sheet material because the other references, while teaching the desirability of doing so, lack explicit descriptions and drawings as to how to accomplish the actual construction of various types of tubes for nerve regeneration, which Stensaas does teach. The ordinary artisan, searching for information to fabricate nerve regeneration tubes, would find the teachings of Stensaas and find it *prima facie* obvious to use his disclosure in

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combination with the other references because Stensaas supplies the explicit teachings that the other references lack concerning nerve regeneration tube construction.

4. Applicant's arguments filed 8/11/03 have been fully considered but they are not persuasive. It is not persuasive to argue the Stensaas reference in isolation from the other references by indicating that Stensaas does not teach collagen materials, but teaches a nerve prosthesis made out of a resilient material "impermeable to fluids associated with nerve tissue." It is pointed out that the Examiner does not rely on Stensaas to teach the collagen material, or any material for that matter, but for information regarding the general fabrication of nerve regeneration tubes using a single sheet of material as a starting point.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

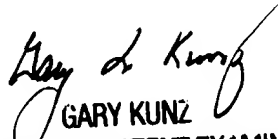
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

December 8, 2003



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600